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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,336	03/23/2004	Jacques Jolivet	PHARMA-357	2203

24999 7590 12/19/2006
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EXAMINER	
RAE, CHARLESWORTH E	
ART UNIT	PAPER NUMBER
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/19/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/806,336	JOLIVET ET AL.	
	Examiner	Art Unit	
	Charleswort Rae	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-15 and 17-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-15 and 17-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments, filed 10/2/06, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of actions being applied to the instant application.

The amendment, filed 10/2/06, has been entered, which renders the Notice of Appeal mute. In view of the newly applied rejections summarized below, the finality of the Office action is hereby withdrawn.

Response to Declarations

Applicant's declarations under 37 CFR 1.132, filed 10/2/06, have been considered and made of record. It is noted that the deficiency in the declarations under 37 CFR 1.132 filed October 11, 2005, has been corrected by the filing of the new declarations of 10/2/06. However, the withdrawal of the rejection renders the declarations moot.

Status of the Claims

Claims 1, 3-15, and 17-60 are currently pending and are the subject of this Office Action.

Nonstatutory Obviousness-Type Double-Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible

harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-15, and 17-60 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 3, 9, 10, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 30, 31, 32, 33, 34, 35, and 36 of U.S. Patent 6,630,480 (Gourdeau '480), in view of U.S. Patent 6,747,036 (Gourdeau '036), in view of U.S. Patent 6,800,639 (Giles '639), and further in view of U.S. Patent 5,817,667 (Chu '667), and further in view of De Bono et al.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are either anticipated by, or would have been obvious in view of the referenced claims.

In particular, claim 1 of Gordeau '480 recites a method for treating a patient with leukemia comprising administering to said patient having chronic myelogenous leukemia or acute myelogenous leukemia, a therapeutically effective amount of a compound having "formula I." Unlike the claims of the instant application (i.e. claims 1, 3-15, and 17-60), the method of said reference claim 1 does not disclose the limitations of a continuous infusion for a period of at least 72 hours wherein a steady state plasma concentration of troxacitabine of 0.03 to 2.0 μM is achieved during the administration. Specifically, the method of claim 1 of the reference is a one-step method for treating a patient with leukemia comprising administering a therapeutically effective amount of troxacitabine. Although claim 1 of Gordeau '480 does not recite a specific mode for administering the desired therapeutically effective amount of troxacitabine to a patient, or a specific period of time for administering the desired therapeutically effective amount of troxacitabine to a patient, or the specific steady state plasma concentration of troxacitabine to be achieved during the administration of troxacitabine to a patient, someone of ordinary skill in the art would reasonably conclude that it is necessary for troxacitabine to be administered to a patient via a particular mode, for a particular period of time, which would necessarily achieve a particular steady state plasma concentration of troxacitabine during the administration of the drug, in order to deliver the desired therapeutically effective amount of troxacitabine to a patient in view of the specification. To the extent that reference claim 1 does not recite limitations that are necessary to practice the referenced invention as claimed, it is reasonable to use the

specification as a dictionary to derive the implied meaning of the term therapeutically effective amount of troxacitabine (see MPEP 2111.01).

Gordeau '480 specification teaches that the desirable blood levels of troxacitabine may be maintained by a continuous infusion to provide about 0.01 to about 5.0 mg/kg/hour or by intermittent infusions containing about 0.4 to about 15 mg/kg of the active ingredient (see Specification, column 6, lines 1-5). Also, Example 2 of the reference specification discloses that twelve patients were treated with an initial course at daily doses of 0.72 mg/m2 (4 patients), 1.08 mg/m2 (5 patients), 1.62 mg/m2 (3 patients) given as a daily infusion over 30 minutes for 5 consecutive days (see Specification, column 10, lines 41-61). The step of administering the troxacitabine for 5 consecutive days, clearly overlaps with the limitation of 3 to 7 consecutive days as recited in the instant claims (i.e. instant claims 23, 24, 25, 27, and 28). The reference specification further teaches that the active ingredient is administered to achieve peak plasma concentrations of from about 1 to about 75 μM (see Gordeau '048, column 5, lines 61-64). This range overlaps with the range of the steady state plasma concentration of troxacitabine recited in the claims of the instant application. Further, claims 1, 14, 15-21, and 30-36 of said reference teaches therapeutically effective amounts of troxacitabine in terms of dosage in mg/kg/day (e.g. claims 14 and 30 recite 0.1-750 mg/kg of body weight per day) or mg/m2/day (i.e. claims 17 and 33 recite 1.08 mg/m2-1.62 mg/m2/day). Based on the above, someone of skill in the art would surmise that a therapeutically effective amount of troxacitabine when given its broadest reasonable interpretation under these circumstances encompass the continuous intravenous administration of troxacitabine daily via a 30-minute infusion for a period of 5 days to achieve a steady state plasma concentration of troxacitabine of about 1 to about 75 μM (see Gordeau '048,

column 5, lines 61-64). The limitations of the instant claims discussed above are considered obvious variants of the above expressed or implied limitations of the referenced claims because administering a therapeutically effective amount of troxacitabine necessarily encompasses the administering of said troxacitabine via a continuous infusion over at least a 72 hour period, which would achieve a steady state plasma concentration of troxacitabine within the range of 0.03 to 2.0 μM during the administration in order to be therapeutically effective. However, Gordeau '480 does not teach the following limitations recited in the above instant claims: lung cancer, prostate cancer, bladder cancer, colorectal cancer, pancreatic cancer, renal cancer, hepatoma, gastric cancer, breast cancer, ovarian cancer, soft tissue sarcoma, osteosarcoma, hepatocellular carcinoma, skin cancer, or troxacitabine in combination with at least one or more therapeutic agents, including nucleoside analogue, chemotherapeutic agent, multidrug resistance reversing agents, and biological response modifiers, or repeating administering troxacitabine by continuous infusion at intervals of every 4 weeks , or every 3 weeks, or every 5 weeks.

Gordeau '036 teaches a method of treating leukemia comprising administering synergistic combinations of troxacitabine and doxorubicin (i.e. reference claims 1 and 11) and said combinations further comprising administering a multidrug resistance reversing agent or a biological response modifier (i.e. reference claims 4 and 5), or a biological response modifier (i.e. reference claims 6, 7, and 8). Gordeau '036 also teaches the sequential administering of troxacitabine and doxorubicin (.i.e. reference claim 9) and the simultaneous administering of troxacitabine and doxorubicin (.i.e. reference claim 10).

Giles '639 teaches a method of treating a patient having pancreatic cancer comprising administering a therapeutically effective amount of troxacitabine and gemcitabine, wherein the

troxacitabine is administered at a dose of between 1 mg/m2 and 8 mg/m2 (.i.e. reference claims 17, 18, and 26).

Chu '667 teaches a method of treating cancer comprising administering to a host animal an effective amount of a compound such as troxacitabine (.i.e. reference claims 1, 2, 3, 4, 5, 6, 7, and 17). Although Chu '667 does not specifically teach renal cancer, bladder cancer, breast cancer, gastric cancer, ovarian cancer, soft tissue sarcoma, skin cancer, osteosarcoma, or rectal cancer, reference claim 1 encompasses these cancers. Further, someone of ordinary skill in the art at the time the instant application was filed would have found it obvious to treat these tumors with the method of Gordeau '480, in view of Gordeau '036, in view of Giles '639, and in view of Chu '667.

De Bono et al. (J. Clin. Oncol. 2002: 20(1): 96-109, abstract only) teach the step of repeating administering troxacitabine as a 30-minute continous infusion daily for five days every 3 to 4 weeks at a dose of 1.5 and 1.2 mg/m2/day, and possibly less frequent schedules. De Bono et al. also disclose that treatment was often delayed one additional week for complete resolution of hematologic effects. Although De Bono et al. do not specifically teach the step of repeating administering troxacitabine at intervals of every 5 weeks, someone of ordinary skill in the art would have found this obvious to repeat the step of administering troxacitabine at intervals of every 5 weeks in view of De Bono et al., in view of Gordeau '480, in view of Gordeau '036, in view of Giles '639, and further in view of Chu '667.

Thus, claims 1, 3-15, and 17-60 are deemed obvious variants of the limitations of the patented subject matter claimed in Gordeau '480, in view of Gordeau '036, in view of Giles '639, in view of Chu '667, and further in view of De Bono et al.

In addition, claims 1, 3-15, and 17-60 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the following: claims 11-21 of copending Application No. 10/824,563; claims 22-29 of copending Application No. 10/107,795, and claims 1-31 of copending Application No. 10/286,960, respectively, in view of Gordeau '480, in view of Gordeau '036, in view of Giles '639, in view of Chu '667, and further in view of De Bono et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are obvious variants of each other for essentially the same reasons stated above.

This is a provisional obviousness-type double pantenting rejection because the conflicting claims of the copending applications have not in fact been patented.

Claim rejections – 35 USC 112 – Second Paragraph

The following is a quotation of the second paragraph of 35 USC 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-15, and 17-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the term "effective amount," but fails to state the specific effect which is to be achieved even though more than one effect can be implied from the specification. Is it a "effective amount" to reduce tumor burden? Or, is it an "effective amount" to inhibit viral replication? In view of the fact that troxacitabine is known to exhibit both antiviral and anti-cancer activity, and certain viruses are implicated in causing certain cancers, an effective amount of troxacitabine could be construed as

being effective to inhibit either viral or cancer activity. This limitation is indefinite because it is not clear what "effective amount" means.

It is noted that this rejection may be overcome by replacing the confusing term with the language "effective amount to achieve tumor reduction" provided support is found in the specification as originally filed (see Specification, page 13, line 33 to page 14, line 3).

Independent claim 8 is rejected under U.S.C. 112, second paragraph, for the same reason stated above.

Also, dependent claims 3-12, 23-28, 33-53, and 58-60 are rejected under U.S.C. 112, second paragraph, for the same reason stated above as these claims fail to correct the deficiency in the claim from which they depend.

Claim 13 recites the language "administering to said patient troxacitabine or a pharmaceutically acceptable salt thereof by continuous infusion for a period of at least 72 hours at a dose of 0.72 to 12.5 mg/m2/day," without stating the effect to be achieved even though multiple effects can be implied. Is the effect to be achieved to "reduce tumor burden?" Or, is the effect to be achieved to "inhibit viral replication?" This limitation is indefinite because it is not clear what effect is to be achieved.

It is noted that this rejection may be overcome by amending said claim to recite the language "effective amount to achieve tumor reduction" provided support is found in the specification as originally filed (see Specification, page 13, line 33 to page 14, line 3).

Dependent claims 14-15, 17-22, 29-32, and 54-57, are rejected under U.S.C. 112, second paragraph for the same reason stated above as these claims fail to correct the deficiency in claim 13.

Claims 4,18, and 49 recite the phrase "wherein said cancer is acute myelogenous leukemia, ..." It is unclear whether "said" refers to a specie of the Markush group of cancers recited in claim 1 or a subspecie of the Markush group (i.e. a subspecie of leukemia). This limitation is indefinite as it lacks adequate antecedent basis. It is suggested that this rejection may be overcome by replacing the word "said" with the word "the."

Dependent claims 5, 19, and 50 are similarly rejected for the same reason stated above as these claims fail to correct the deficiency of the claims from which they depend.

Claim rejections – 35 USC 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-15, and 17-60, are rejected under U.S.C. 103(a) as being unpatentable over De Bono et al. (J. Clin. Oncol. 2002: 20(1): 96-109, abstract only), in view of Chu et al. (US patent 5,817,667), and further in view of Benet LZ et al. (Benet et al. Pharmacokietics: The dynamics of drug absorption, distribution, and elimination. In, Goodman & Gilmans: The Pharmacological Basis of Therapeutics, 9th edition (1996): pages 3 and 18).

De Bono et al. teach the pharmacokinetics and pharmacodynamics of troxacitabine in thirty-nine patients with advanced solid malignancies at eight dose levels ranging from 0.12 to 1.8 mg/m2/day via a 30-min intravenous infusion for five days. De Bono et al. teach that the pharmacokinetics of troxacitabine is dose-independent wherein the mean (SD) values for the volume of distribution at steady-state and clearance (Cl) were 60 (32 L and 161 (33) ml/min, respectively, on day 1. After treatment on the fifth day, terminal half-life values averaged 39 (63) hours, and Cl, was reduced by approximately 20%, averaging 127 (27) ml/min. The principal mode of drug elimination was renal. A patient with metastatic ocular melanoma experienced a partial response. De Bono et al. further disclose that broad disease-directed evaluations of troxacitabine as a 30-minute infusion daily for 5 days every 4 weeks at a dose of 1.5 - 1.2 mg/m2/day, and possibly less frequent schedules, were warranted. Clearly, De Bono et al. teach a method for treating patients with solid malignancies, including ocular

melanoma, comprising administering an effective amount of troxacitabine via a 30-min intravenous infusion for a period of 120 hours (5 days) wherein a steady state plasma concentration of troxacitabine was achieved during the administration. That a patient with melanoma experienced a partial response is evidence that the dose range from 0.12 to 1.8 mg/m2/day via a 30-min intravenous infusion for five days is a therapeutically effective amount of troxacitabine. However, De Bono et al. do not teach steady state plasma (or blood) concentration of troxacitabine of 0.03 to 2.0 μM achieved during the administration, Further, independent claims 1, 13, and 47 of the instant application recite the limitation "continuous infusion for a period of at least 72 hours." Although this limitation could be construed to mean a continuous infusion that must be infused continuously over a period of at least 72 hours, this limitation when given its broadest reasonable literal interpretation encompasses any continuous infusion, regardless of the actual infusion time, administered for a period of at least 72 hours. It is also common knowledge in the pharmacokinetic art that it requires at least four to five terminal half-lives to eliminate all of the infused drug from the body of a patient following administration of a dose of drug. Thus, the De Bono et al. once daily continuous infusion of troxacitabine intravenously infused over 30 minutes for a period of five days to provide a continuous amount of troxacitabine in the blood stream of patients with solid tumors who were administered the drug satisfies the "continuous infusion for a period of at least 72 hours" limitation recited in the claims of the instant application. As stated above, De Bono et al. do not teach steady state plasma (or blood) concentration of troxacitabine of 0.03 to 2.0 μM achieved during the administration, nor do they teach

leukemia or lymphoma, but suggest further broad disease-directed evaluations of troxacitabine.

Chu et al. (US Patent 5,817,667) teach a method for treatment of cancer in humans and other host animals comprising administering an effective amount of troxacitabine (column 3, lines 21-52). Chu et al. specifically teach that various cancer cells lines are sensitive to troxacitabine, including leukemia, lymphoma, prostate, bladder, lung, colorectal, breast, pancreas, liver, ovarian cancers (see Figure 4). Chu et al. also disclose that troxacitabine is preferably administered to achieve peak plasma concentrations of the active compound of about 0.00001-30mM, by the intravenous injection of a solution or formulation of the active ingredient, optionally in saline, or an aqueous medium or administered as a bolus of the active ingredient. The range of steady state plasma concentration of troxacitabine recited in the instant application overlaps with the range of steady-state plasma level of troxacitaine taught by Chu et al. However, Chu et al. do not teach a "continuous infusion for a period of at least 72 hours." In view of the suggestion provided by De Bono et al., someone of skill in the art would have found it obvious to combine Chu et al. and De Bono et al. to create a method of treating patients with solid tumors and leukemia by administering a 30-minute continuous infusion of troxacitabine daily for five days to achieve steady-state plasm levels of troxacitabine of about 0.00001 – 30 mM.

Further, Benet LZ et al. (Benet et al. Pharmacokietics: The dynamics of drug absorption, distribution, and elimination. In, Goodman & Gilmans: The Pharmacological Basis of Therapeutics, 9th edition (1996): page 18) teach that Clinical Pharmacokinetics

attempts to provide both a more quantitative relationship between dose and effect and the framework with which to interpret measurements of concentration of drugs in biological fluids (page 18, column 1, lines 2-6). Benet LZ et al. further teach that the various physiological and pathophysiological variables that dictate adjustment of dosage in individual patients often do so as a result of modification of pharmacokinetic parameters and that the three most important parameters are clearance, volume of distribution, and bioavailability; of lesser importance are the rates of availability and distribution of the agent (page 18, column 1, lines 10-19). In fact, someone of skill in the art can manipulate certain pharmacokinetic equations to determine the infusion rate of a particular drug to achieve or maintain steady-state concentrations of the drug within a known therapeutic range (e.g. Dosing rate (Do) = Clearance (Cl) x steady-state concentration (Css); and Cl = Dose/ total area under the curve that describes the concentration of drug in the systemic circulation as a function of time (AUC) (see page 18, columns 1-2). Thus, Benet et al. at least suggest, if not provide further motivation, to someone of skill in the art to manipulate the pharmacokinetic variables (e.g. dosing rate or infusion rate) in view of De Bono et al., and further in view of Chu et al. in order to achieve and maintain steady-state blood levels of troxacitabine of about 0.00001 – 30 mM in patients suffering from solid malignancies and leukemia wherein the troxacitabine is administered via a continuous infusion for a period of at least 72 hours at the time the instant invention was made.

Weitman S, et al. (The new dioxolane, 9-)-2'-Deoxy-3'-oxacytidine (BCH-4556, Troxacitabine), activity against pancreatic human tumor xenografts. Clinical Cancer Research. 6:1574-1578, April 2000) is cited only to show the state of the art.

Thus, based on the suggestion of De Bono et al. that further broad disease-directed evaluations of troxacitabine are required, and the suggestion of Benet et al. that the dosing rate of a drug may be manipulated to maintain steady-state blood concentration of a drug, someone of skill in the art at the time the instant invention was made would have found it obvious to combine the teachings of De Bono et al., in view of Chu et al., and further in view of Benet et al. to create the inventive concept of the instant application with a reasonable expectation of success.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charlesworth Rae whose telephone number is 571-272-6029. The examiner can normally be reached between 8 a.m. to 4:30 p.m. Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http:pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 800-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

8 December 2006
CER

Ardin H. Marschel 12/9/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER